

Action, Applicants have herein amended claims 1 and 16 to clarify that the composite material is ductile. These claims also now particularly specify at least one bioceramic or bioglass reinforcing component as a bony ongrowth agent. Support for the amendments exists throughout Applicants' specification, for example, at page 4, lines 11-23, page 6, lines 9-11 and in Figure 1. Reconsideration and allowance of this application is therefore respectfully requested.

In the Action, claims 1-6 and 11-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,084,051 to Tormala et al. ("the '051 patent"). Claims 1-8 and 11-22 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over the '051 patent. Similarly, claims 9-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the '051 patent as applied to claims 1-8 and 11-22 above, and further in view of the article *In Vivo Evaluation of Hydroxyapatite Reinforced Polyethylene Composites* to Bonfield et al. ("Bonfield").

It is respectfully asserted that the afore-cited references, whether viewed alone or in any combination, neither disclose nor suggest the presently claimed invention for the following reasons.

The '051 patent discloses a biocomposite material, wherein the ceramic of the biocomposite "*can be porous or nonporous ceramic block*, which has been manufactured e.g. by sintering of ceramics given on side 1 such as of calcium phosphates, fluoroapatites, calcium carbonates, magnesium calcium phosphates, bioglasses, glass ceramics or of mixtures of ceramics" (Col. 6, lines 41-46, emphasis added). In further accordance to the '051 patent, the "material component (2) of these biocomposites gives to them the toughness, strength and security of handling, because the strong and tough material component supports the brittle bioceramic component as a consequence of the high strength, toughness and high modulus of reinforcement elements. Therefore, only very large external stresses can cause

deformations in the bioceramic components” (Col. 7, lines 40-54).

However, such a biocomposite material as described in the ‘051 patent does not disclose nor suggest Applicants’ *ductile* biodegradable and bioactive composite material comprising e.g. two different reinforcing components and a matrix material, as particularly claimed herein. As described in Applicants’ specification at page 4, line 20 continuing to page 5, line 4, reinforced composite devices described in this invention have improved mechanical properties compared to non-reinforced devices, because reinforcement changes the behavior of material from brittle to ductile and thus makes the device more reliable under load. Due to, for instance, controlled manufacturing stages and *mixing of matrix and ceramic reinforcing elements*, the amount of both reinforcing element types is easily controlled. This is an important advantage, because the ratio of elements affects the mechanical properties of the device. Also, the amount of the ceramic reinforcing element affects the bioactivity of the device.

Moreover, the inventors unexpectedly found that e.g. reinforcing resorbable fibers could be added to a polymer matrix including bioceramics or bioglass and the resultant composite material would have desirable *ductility*, as opposed to brittleness, while also having strengthened mechanical properties. *See* Applicants’ specification at pages 7-8.

Accordingly, one trying to increase the ductility of materials usually would not think of using brittleness enhancing materials. Additionally, Applicants’ bioceramic or bioglass reinforcing component advantageously acts as a bioactive, bony ongrowth agent and may provide a reservoir of calcium and phosphate ions, thus accelerating the healing time for bone fractures, as described in Applicants’ specification at page 6, lines 9-13.

In furtherance to the above, it is asserted that the addition of Bonfield, which was cited by the Examiner in the rejection of Applicants’ dependent claims 9 and 10 as describing particular volume fractions, does not disclose nor suggest Applicants’ advantageous

composite material for reasons set forth above in connection with Applicants' independent claims.

It is respectfully submitted that the subject application is now in condition for immediate allowance. A Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

KENYON & KENYON

*Paul M. Richter, Jr.*

Dated: 8/10/00

By: Mary C. Weiner Reg No. 30,333  
Paul M. Richter, Jr. (Reg. No. 36,254)

KENYON & KENYON

One Broadway

New York, New York 10004

(212) 425-7200 (telephone)

(212) 425-5288 (facsimile)